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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/555,949 06/06/00 ISHIKAWA T 2499USOP

023115 HM12/0523
TAKEDA PHARMACEUTICALS AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
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LINCOLNSHIRE IL 60069

EXAMINER

BERCH, M

ART UNIT**PAPER NUMBER**

1624

DATE MAILED:05/23/01 *G*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/555,949

Applicant(s)

ISHIKAWA ET AL.

Examiner

Mark L. Berch

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1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 5, 12, drawn to cephalosporins (Y =S), classified in class 540, subclass 225, 227.
- II. Claims (none), drawn to Oxacephems (Y=O), classified in class 540, subclass 301.
- III. Claims (none), drawn to Carbacephems (Y=CH₂), classified in class 540, subclass 205.

Claims 1-4, 6-11, and 13-28 link inventions I, II and III. These claims are examined to the extent that they read on the elected invention.

The inventions are distinct, each from the other because of the following reasons: Each Y choice provides a different heterocyclic core. Group I is distinct in having a S atom present; Group II has O present in the core, and Group III has only the N. These are different categories of antibiotics, and a reference showing e.g. a cephalosporin would not itself render obvious a carbacephem.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mark Chao on 5/9/01 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims

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(none) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-4, 6-11, and 13-28 are rejected as being drawn to an improper Markush Group. The claims are drawn to multiple inventions for reasons set forth in the above requirement for restriction. This does not constitute an art recognized genus. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter (limitation of Y to just S) will overcome the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 14-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The scope of "group convertible to a phosphono group" is unclear. Would that include simply removing the group and replacing it with phosphono? If so, then pretty much anything can be R¹. If not, convertible under what conditions? If a specific R¹ group was not be converted by e.g. hydrolysis, how would one of ordinary skill in the art

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know that there wasn't some as yet untried method which would work? How could one ever be sure that a given R^1 group simply could not be converted to phosphono?

2. Protected (in claim 2) against what? These are final products, so what is there to protect against? As there is no such thing as a universal protecting group, correct selection of a protecting group requires some knowledge of what is being protected against.

3. The term "group having a linkage through a carbon atom" is open-ended. It says nothing about the structure of the group, other than it must have a carbon present with a free valence.

4. "Substituted" with what?

5. "Heterocyclic" is indefinite. What is the size of the ring? What is the number and nature of the heteroatoms; all the claim says is that there must be at least one N present? Can the ring be fused or spiroconnected to another ring, and if so, what kind of ring? Can the ring be bridged? Unsaturated? Cf. *In re Wiggins*, 179 USPQ 421, 423.

6. The claim 15 step of "subjecting a compound ... to the reaction in which the quaternized -ammonium is formed" is unduly functional. It simply states what is one of the starting materials and states the final product, but not what the actual step is.

7. Further, that step as written will not give the zwitterion set forth in claim 1. Note that claim 15 starts with the acid, and hence will end with the acid since there is no step to remove that proton.

8. Claim 16 is intended as a composition claim, but there is no carrier recited. A proper pharmaceutical composition requires a carrier. In view of claim 17, this claim is not really needed.

11. “Quaternized” with what? This simply says that a 4th group is attached to the N but does not say what the group is.

(IX)

It can thus be seen that the compound has the same structure as the compounds here, with the sole exception that the reference has R₁ as protected amino, while the claims have amino with phosphono or a group convertible thereto. However, ordinary

protecting groups can be removed and then replaced with phosphono, and hence under the broad reading of the claim terminology, the claims are anticipated, since they would cover ordinary protecting groups. The use and synthesis are the same.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 9-100283 in view of Teraji(1986) or Teraji (1981).

The primary reference is discussed above. Teraji (1986) (see abstract) shows the same phosphono groups that are recited in the instant claim 3. Further, it is in the context of virtually identical compounds. The sole difference between this secondary reference and the current claims is that the reference has an unfused pyridinium at the 3-position while applicants have a fused pyridinium. The reference notes the advantages arising from the use of the phosphono derivatives, viz., getting the improved solubility (see Column 14, lines 3-10). One of ordinary skill in the art would be motivated to obtain this advantage in the virtually identical compounds of the primary reference and hence the claimed compounds would be obtained.

Alternatively, the phosphono group itself is known as a protecting group, as shown by the other secondary reference, at column 6, line 56. Hence, it would be understood as included in the disclosure of protected amino in the primary reference.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.



Mark L. Berch
Primary Examiner
Art Unit 1624

May 16, 2001